

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

BAUSCH & LOMB INCORPORATED,

Plaintiff,

- VS -

FAEZEH MONA SARFARAZI, M.D.,

Defendant.

**COMPLAINT FOR
DECLARATORY
RELIEF**

Civil Action No.

Bausch & Lomb Incorporated ("B&L"), by and through its counsel, Nixon Peabody LLP and Irell & Manella LLP, as and for its Complaint against Defendant Faezeh Mona Sarfarazi, M.D. ("Sarfarazi"), alleges as follows:

NATURE OF THE CASE

1. In July 2003, Plaintiff B&L licensed intellectual property owned by Defendant Sarfarazi relating to a single piece, multiple optic accommodating intraocular lens that could be implanted into the human eye (the "Licensed Product"). Both parties hoped that B&L would be able to develop a lens for cataract patients that would enable the patients' eyes to focus on different distances without the aid of glasses. B&L agreed to pay Sarfarazi millions of dollars and use reasonable commercial efforts to develop the lens. B&L did both of these things.

2. Over five years, B&L paid Sarfarazi \$9.5 million, dedicated an entire development team to the project, and spent at least an additional \$11.5 million developing the lens. As part of its efforts to develop the lens, B&L created test protocols, conducted multiple clinical trials involving more than seventy participants, and designed its own improvements to the lens in an attempt to make the lens functional. However, despite these reasonable commercial efforts and its significant investment of resources, the lens never functioned as

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planned, and B&L concluded that further re-design of the lens was pointless. As a result, in mid-2007, B&L exercised its right to terminate the parties' License Agreement.

3. Since the License Agreement's termination, Sarfarazi has threatened to sue B&L for breach of contract, idea misappropriation and other related claims. Sarfarazi also complains that B&L has allegedly not given her information to which she is allegedly entitled pursuant to the termination clause of that agreement, and that B&L has supposedly misappropriated her ideas by filing a patent application that does not name her as a co-inventor, even though the ideas in the application did not belong to Sarfarazi. B&L has tried to mollify Sarfarazi by giving her more information regarding B&L's efforts to develop the lens than she is entitled to receive under the parties' agreement. B&L has also been willing to meet with Sarfarazi to identify and discuss what additional information or materials Sarfarazi would need to continue development of the lens herself. B&L's efforts have been unsuccessful. Sarfarazi continues to threaten B&L with litigation, and her threats are impairing B&L's ability to protect its intellectual property.

4. Plaintiff B&L seeks a judgment declaring that: (i) B&L did not breach the parties' License Agreement by not providing defendant Sarfarazi with certain information and clinical data after the License Agreement's termination; (ii) B&L did not breach the License Agreement because it provided defendant Sarfarazi with the Termination License she was entitled to after the License Agreement's termination; (iii) B&L did not breach the License Agreement because it used reasonable commercial efforts in managing clinical trials and developing the lens; (iv) B&L did not breach the License Agreement's confidentiality provision by filing a patent application pertaining to Iteration #8 of the lens; (v) B&L did not misappropriate defendant Sarfarazi's ideas by filing a patent application that did not name Sarfarazi as a co-inventor; and (vi) Sarfarazi's

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sole mechanism for challenging B&L's decision to terminate the License Agreement is arbitration and the time for Sarfarazi to commence such an arbitration has expired.

JURISDICTION AND PARTIES

5. Plaintiff B&L is, and at all times herein mentioned was, a corporation organized and existing under the laws of the State of New York with its principal place of business in the Western District of New York.

6. Defendant Sarfarazi is an individual who, upon information and belief, is a citizen of California.

7. The Court has original jurisdiction over this action under 28 U.S.C. § 1332 in that it is a civil action between citizens of different states in which the matter in controversy exceeds, exclusive of costs and interest, seventy-five thousand dollars (\$75,000.00).

VENUE

8. Venue for this action properly lies in this District pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of conduct that defendant has claimed is a breach of the License Agreement or idea misappropriation occurred in this District.

THE LICENSE AGREEMENT

9. On or about July 18, 2003, B&L and Sarfarazi entered into a license agreement (the "License Agreement"), whereby Sarfarazi granted B&L an exclusive fully paid-up license for the Licensed Product.

10. The License Agreement required B&L to use reasonable commercial efforts to develop the Licensed Product. The objective of the License Agreement was for B&L to develop and commercialize a twin lens accommodating intraocular lens system for implantation into the human eye, which would consistently provide at least 3 diopters of objective accommodation.

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The idea behind development of the lens was to utilize the eye's muscles to alter the focus of the lens, enabling cataract patients to substantially improve their ability to focus at different distances without the aid of glasses or a multi-focal lens.

11. The License Agreement provided that B&L would give Sarfarazi written monthly updates and meet with her quarterly for the first three years of the term of the License Agreement or until completion of a six month evaluation of 100 eyes during the human clinical study, whichever was later.

12. The License Agreement contained a confidentiality provision preventing the parties from publicly disclosing any information related to the development or commercialization of the Licensed Product, unless the purpose of the disclosure was contemplated by the License Agreement. The License Agreement contemplated that the parties would file patent applications during the term of the License Agreement.

13. The License Agreement provided that B&L could terminate the agreement at any time on sixty days notice to Sarfarazi if B&L had made a commercially reasonable determination that, among other things, there had been a material change in the anticipated efficacy or safety of the lens. The License Agreement also provided that after receiving a termination notice, Sarfarazi would have sixty days to challenge B&L's decision to terminate the License Agreement and that if B&L did not alter its termination decision, Sarfarazi would have, as her sole remedy, ninety days to commence an arbitration proceeding challenging the propriety of B&L's termination decision.

14. Upon termination, the License Agreement provided that B&L would assign and transfer to Sarfarazi all regulatory filings and approvals and clinical data related to the Licensed Product.

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15. Upon termination, the License Agreement provided that B&L would grant to Sarfarazi a non-exclusive, royalty free, perpetual license to the Joint Patents Rights, B&L Technology, and B&L Mold Patent Rights to make, have made, import, offer to sell, rent, or use the Licensed Product (the "Termination License").¹

16. Pursuant to the License Agreement, B&L timely paid Sarfarazi \$9.5 million.

FACTS LEADING UP TO THE PARTIES' CURRENT DISPUTES

17. B&L used reasonable commercial efforts to develop the Licensed Product.

18. B&L developed eight different iterations of the lens. Each subsequent iteration of the lens presented new technological and engineering challenges, but each iteration was intended to create a lens that would consistently provide a level of accommodation in excess of 3 diopters.

19. B&L conducted four human clinical trials testing three different iterations of the lens. B&L implanted different iterations of the lens into the eyes of over seventy participants. B&L spent approximately \$1.4 million on the clinical trials. In performing the clinical trials, B&L followed appropriate international guidelines, national regulations of the respective countries involved, and cooperated with local hospital ethics boards. B&L followed standard industry practice in performing the clinical trials outside the United States.

20. B&L assigned top personnel to the development and manufacture of the lens. Regular meetings were held about the status of the project involving core personnel. In total, B&L spent over \$20 million developing the Licensed Product.

¹ The terms "Joint Patents Rights," "B&L Technology" and "B&L Mold Patent Rights" are terms that are defined in the License Agreement.

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21. As a result of its extensive research and development efforts, B&L employees Josh Enin and Gary Richardson developed Iteration No. 8 of the lens ("Iteration #8"). Iteration #8 was not Sarfarazi's idea.

22. In November 2006, B&L disclosed Iteration #8 to Sarfarazi. Sarfarazi did not claim that Iteration #8 was her idea.

23. On or about December 20, 2007, B&L submitted Application No. 11/961,420 for a U.S. patent of claims based on Iteration #8 ("Application '420"). B&L appropriately named Josh Enin and Gary Richardson as the inventors.

24. B&L's filing of patent applications based upon its research and development efforts to develop the Licensed Product was B&L's regular practice during the term of the License Agreement. Before B&L terminated the License Agreement, Sarfarazi never complained about patent applications B&L filed regarding its development of the Licensed Product. B&L's practice of filing patent applications to protect intellectual property that B&L created due to its development efforts regarding the Licensed Product was contemplated by the License Agreement.

25. After extensive research and development, in late 2006 or early 2007, B&L determined that a material change had occurred regarding the anticipated safety and efficacy goals of the lens. B&L also determined that despite its considerable development efforts, it was no longer reasonable to believe that further re-design of the lens would result in the lens being able to achieve at least 3 diopters of objective accommodation. As a result, on or about February 7, 2007, B&L notified Sarfarazi that B&L was exercising its right to terminate the License Agreement.

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26. Sarfarazi had until about April 9, 2007 to discuss with B&L its decision to terminate the License Agreement. During this sixty-day period, Sarfarazi did not discuss with B&L its decision to terminate the License Agreement.

27. The License Agreement was terminated on or about April 9, 2007.

28. Per the License Agreement, Sarfarazi had until about July 9, 2007 to commence an arbitration challenging B&L's decision to terminate the License Agreement. Because the parties were engaged in on-going settlement negotiations, B&L granted Sarfarazi several time extensions to commence such an arbitration. The last extension was given to Sarfarazi on February 28, 2008, and it expired at the end of March 2008. B&L has not granted Sarfarazi any other time extensions to commence an arbitration.

29. Sarfarazi has not commenced any arbitration proceedings challenging B&L's decision to terminate the License Agreement. Her time to commence such an arbitration has expired.

30. Despite arbitration being Sarfarazi's sole mechanism for challenging B&L's termination decision and the time for commencing such an arbitration having expired, Sarfarazi claims that she can still challenge B&L's decision to terminate the License Agreement, and she can do so by commencing litigation in court.

31. Sarfarazi has threatened to file a complaint in court challenging B&L's decision to terminate the License Agreement.

32. Upon termination, the License Agreement provided that B&L would assign and transfer to Sarfarazi regulatory filings and approvals and clinical data related to the Licensed Product. B&L did so. It provided Sarfarazi with the regulatory filings and approvals and clinical

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data that she was entitled to receive under the License Agreement. As a courtesy, B&L also provided Sarfarazi with additional information that it was not required to provide to Sarfarazi.

33. In June 2007, Sarfarazi claimed that B&L was purportedly in breach of the License Agreement because B&L had allegedly provided her with incomplete clinical data. B&L denied that it was in breach of the License Agreement, but gave Sarfarazi the clinical data she requested, including data from clinical studies that had not yet been finalized. In November 2007, Sarfarazi again claimed that B&L was supposedly in breach of the License Agreement because B&L had allegedly not given her final clinical study reports. B&L denied that it was in breach of the License Agreement but, as a courtesy, provided Sarfarazi with the final clinical study reports she requested. Despite receiving more information than she is entitled to receive under the License Agreement, Sarfarazi continues to claim that B&L is in breach of the License Agreement because B&L has not provided her with certain clinical study data.

34. In or about September 2008, Sarfarazi claimed that B&L was in breach of the License Agreement because B&L purportedly failed to grant her the Termination License. B&L denies it is in breach of the License Agreement because Sarfarazi was granted the Termination License by the terms of the License Agreement. Sarfarazi also claimed that B&L is in supposed breach of the License Agreement because B&L allegedly failed to give her monthly written project updates and meet with her quarterly. B&L denies it is in breach of the License Agreement because it has provided her with monthly project updates and met with her as required by the License Agreement.

35. Also in September 2008, Sarfarazi claimed that B&L purportedly misappropriated her intellectual property by filing Application '420 and not naming her as an inventor. B&L denies it misappropriated Sarfarazi's ideas because Iteration #8 was not Sarfarazi's idea.

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Sarfarazi's claim has no merit, but it nevertheless clouds B&L's ability to develop its intellectual property.

CURRENT DISPUTES

36. A present and actual controversy has arisen and now exists within the Court's jurisdiction between B&L and Sarfarazi concerning their respective rights, duties, and obligations under the License Agreement. As described above, Sarfarazi claims that B&L has purportedly breached its obligations under the License Agreement and has misappropriated her ideas. B&L denies that it has breached the License Agreement in any way. B&L also denies it has misappropriated Sarfarazi's ideas.

37. Sarfarazi has also threatened to commence litigation against B&L challenging its decision to terminate the License Agreement, even though Sarfarazi's sole mechanism for challenging the License Agreement's termination was arbitration and the time to commence such an arbitration has expired.

38. In September 2008, Sarfarazi provided B&L with a letter detailing Sarfarazi's claims of purported breach of contract and idea misappropriation. Sarfarazi claims that B&L's supposed illegal conduct has caused her damages in the millions of dollars. In her September 2008 letter, Sarfarazi claims an ownership interest in Iteration #8. B&L denies Sarfarazi's claims. In this letter, Sarfarazi also threatens to commence litigation against B&L for, among other things, breach of contract, idea misappropriation and improperly terminating the License Agreement.

39. Sarfarazi's threat of litigation, her substantial damages claim, and her claim of an ownership interest in Iteration #8 are currently harming B&L. Sarfarazi's threats of litigation and

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her claimed interest in Iteration #8 are materially impacting B&L's ability to develop and protect its intellectual property.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(For A Declaration Pursuant to 28 U.S.C. §§ 2201-2202 That B&L
Did Not Breach The License Agreement)

40. Plaintiff B&L repeats and realleges the allegations of paragraphs 1-39 above, and incorporates those allegations herein by this reference.

41. A judicial declaration of the parties' rights, duties, and obligations is necessary and appropriate at this time under the facts and circumstances alleged above for B&L and Sarfarazi to ascertain their respective rights, duties and obligations with respect to the License Agreement.

SECOND CLAIM FOR RELIEF

(For a Declaration Pursuant to 28 U.S.C. §§ 2201-2202 That B&L
Did Not Misappropriate Sarfarazi's Ideas)

42. Plaintiff B&L repeats and realleges the allegations of paragraphs 1-39 above, and incorporates those allegations herein by this reference.

43. A judicial declaration of the parties' rights, duties, and obligations is necessary and appropriate at this time under the facts and circumstances alleged above in order for B&L and Sarfarazi to ascertain their respective rights, duties and obligations with respect to ownership of the ideas concerning Iteration #8.

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THIRD CLAIM FOR RELIEF

(For a Declaration Pursuant to 28 U.S.C. §§ 2201-2202 That Sarfarazi's Sole Remedy For Challenging B&L's Decision To Terminate The License Agreement Is Arbitration And Her Time To Commence Such An Arbitration Has Expired)

44. Plaintiff B&L repeats and realleges the allegations of paragraphs 1-39 above, and incorporates those allegations herein by this reference.

45. A judicial declaration of the parties' rights, duties, and obligations is necessary and appropriate at this time under the facts and circumstances alleged above in order for B&L and Sarfarazi to ascertain their respective rights, duties and obligations with respect to challenging B&L's decision to terminate the License Agreement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff B&L prays for relief against Defendant Sarfarazi as follows:

1. For a declaration that B&L did not breach the parties' License Agreement by not providing Defendant Sarfarazi with certain information and clinical data after the License Agreement's termination.

2. For a declaration that B&L did not breach the License Agreement because it provided Defendant Sarfarazi with the Termination License to which she was entitled after the License Agreement's termination.

3. For a declaration that B&L did not breach the License Agreement because it used reasonable commercial efforts in managing the clinical trials and development of the lens.

4. For a declaration that B&L did not breach the License Agreement's confidentiality provision by filing a patent application pertaining to Iteration #8 of the lens.

5. For a declaration that B&L did not misappropriate Defendant Sarfarazi's ideas by filing a patent application that did not name Sarfarazi as a co-inventor.

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6. For a declaration that Defendant Sarfarazi's sole mechanism for challenging B&L's decision to terminate the License Agreement is arbitration and the time for Sarfarazi to commence such an arbitration has expired.

7. For such further relief as the Court deems just and proper.

Dated: January 28, 2009
Rochester, New York

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